DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center – WO66-G609
Silver Spring, MD 20993-0002

August 21, 2014

Covidien LLC
Mr. Tim Thomas
Vice President, Medical and Regulatory Affairs
540 Oakmead Parkway
Sunnyvale, California 94085

Re: K141357
Trade/Device Name: Barrx FLEX RFA Energy Generator
Regulation Number: 21 CFR 878.4400
Regulatory Name: Electrosurgical cutting and coagulation device and accessories
Regulatory Class: Class II
Product Code: GEI
Dated: May 22, 2014
Received: May 23, 2014

Dear Me. Thomas:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you; however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set

forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

David Krause -S

for Binita S. Ashar, M.D., M.B.A., F.A.C.S.
Director
Division of Surgical Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Indications for Use Statement

510(k) Number (if known): To be determined

Device Name:

- Barrx FLEX RFA Energy Generator

Indications for Use:

The Barrx FLEX RFA Energy Generator is indicated for use in the coagulation of soft tissue.

The Barrx FLEX RFA Energy Generator is indicated for use in the coagulation of bleeding and non-bleeding sites in the gastrointestinal tract including but not limited to the esophagus. Indications include Esophageal Ulcers, Mallory-Weiss tears, Arteriovenous Malformations, Angiomata, Barrett's Esophagus, Dieulafoy Lesions and Angiodysplasia.

Prescription Use _X__ AND/OR Over-The-Counter Use____
(Part 21 C.F.R. 801 Subpart D) (21 C.F.R. 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE -- CONTINUE ON ANOTHER PAGE IF NEEDED)

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Concurrence of CDRH, Office of Device Evaluation (ODE)

510(k) Summary

SUBMITTER'S NAME, ADDRESS, TELEPHONE NUMBER, CONTACT PERSON AND DATE PREPARED

Covidien llc
540 Oakmead Parkway
Sunnyvale, CA 94085
Phone: (770) 662-0870 ext. 1006
Facsimile: (508) 452-1941
Contact: Tim Thomas
Date Prepared: May 22, 2014

NAME OF SUBJECT DEVICE AND NAME

Barrx FLEX RFA Energy Generator

ESTABLISHMENT REGISTRATION NUMBER/OWNER OPERATOR NUMBER

Establishment Registration Number: 3004904811
Owner/Operator Number: 1282497
Legal Manufacturer: Covidien, llc
15 Hampshire Street
Mansfield, MA 02048
Manufacturing Facility:
Covidien, Formerly BÂRRX Medical, Inc.
540 Oakmead Parkway
Sunnyvale, CA 94085

COMMON OR USUAL NAME

Electrosurgical cutting and coagulation device and accessories

REGULATION DESCRIPTION

Classification: Class II, 21 CFR 876.4400
Product Code: GEI

PREDICATE DEVICES

Barrx™HALO^{FLEX} Energy Generator, 510(k) K092487
HALO^{360} Energy Generator, 510(k) K093855
HALO^{90} Energy Generator, 510(k) K093008

DEVICE DESCRIPTION

The subject device, the Barrx™ Barrx FLEX RFA Energy Generator is a device that is intended to be used with the listed catheters to deliver radiofrequency (RF) energy to the treatment tissue within the gastrointestinal tract through a copper electrode. The catheters include:

- HALO360 Ablation Catheter and Sizing Ballon (K093855)
- HALO90 Ablation Catheter (K093008)
- HALO^{60} Ablation Catheter (K112454)
- HALO^{90} ULTRA Ablation Catheter (K120431)
- Barrx Channel RFA Endoscopic Catheter (K130623)

INDICATION FOR USE

The Barrx FLEX RFA Energy Generator is indicated for use in the coagulation of soft tissue.

The Barrx FLEX RFA Energy Generator is indicated for use in the coagulation of bleeding and non-bleeding sites in the gastrointestinal tract including but not limited to the esophagus. Indications include Esophageal Ulcers, Mallory-Weiss tears, Arteriovenous Malformations, Angiomata, Barrett's Esophagus, Dieulafoy Lesions and Angiodysplasia.

TECHNOLOGICAL CHARACTERISTICS OF DEVICE COMPARED TO PREDICATE DEVICE

As the subject of this submission is a labeling change only, the Barrx FLEX RFA Energy Generator has identical technological characteristics as compared to the predicate, K092487. There have been no design or material changes to the generator since the predicate was cleared on November 10, 2009. There have been minor software changes since the clearance of the K092487 however they did not require a submission and were documented via Letter to File. The difference between the proposed Barrx FLEX RFA Energy Generator and the predicate device (K092487) is the addition of clinical information to the labeling resulting from two published peer-reviewed clinical studies.

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PRINCIPLES OF OPERATION

As the subject of this submission is a labeling change only, the principles of operation of the Barrx FLEX RFA Energy Generator are unchanged and remain identical to the predicate device, K092487, cleared on November 10, 2009.

The Barrx FLEX RFA Energy Generator is an electrosurgical device that utilizes bipolar RF energy to coagulate biological tissue. The Generator is provided with a footswitch that can initiate inflation or deflation of the balloon and initiate or cease delivery of RF energy. The Barrx FLEX RFA Energy Generator is designed to function with a family of single use, disposable Ablation Catheters and Sizing Balloons to deliver the intended therapy. The family of catheters includes:

- HALO360 Ablation Catheter and Sizing Ballon (K093855)
- HALO90 Ablation Catheter (K093008)
- HALO^{60} Ablation Catheter (K112454)
- HALO^{90} ULTRA Ablation Catheter (K120431)
- Barrx Channel RFA Endoscopic Catheter (K130623)

CONCLUSION

As the subject of this submission is a labeling change only, Covidien, llc considers the Barrx FLEX RFA Energy Generator to be substantially equivalent to legally marketed predicates: Barrx™ HALO^{FLEX} Energy Generator (K092487), HAL0^{360} Energy Generator (K093855) and HAL0^{90} Energy Generator (K093008).